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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,793	09/06/2006	Martin Edward Lee Pickford	1450-02100	4654

62763 7590 04/30/2010

Tod T. Tumey
P.O. BOX 22188
HOUSTON, TX 77227-2188

EXAMINER	
LEADER, WILLIAM T	

ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
04/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,793	PICKFORD ET AL.	
	Examiner	Art Unit	
	WILLIAM T. LEADER	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15,17,19-25,27-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17,19-25,27-29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of the papers filed on January 7, 2010, is acknowledged. As noted by applicant, claims 13-30 were submitted in the third preliminary amendment filed on January 26, 2009. After entry of the amendment filed on January 7, 2010, claims 13-15, 17, 19-25, 27-29 and 31-33 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 13-15, 17, 19-25, 27, 28 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickford et al (WO 03/089023) in view of O'Brien et al (US 7,488,343).

5. As indicated in paragraph 11 of the previous office action, the Pickford et al publication (hereinafter Pickford) is directed to the manufacture of metal implants. The implant may be

made of titanium alloy which is very strong and relatively light (page 1, lines 11-12). The implant comprises a metal substrate and a surface layer that is integral with the metal substrate and which incorporates a biocidal metal (page 1, lines 25-29). The integral surface layer may be generated by growing the layer from the metal itself, for example by an anodizing process (page 1, line 34-36). Silver is the preferred biocidal metal (page 2, lines 25-28). In an example at page 5, lines 1-23, an implant made of titanium alloy was anodized in a 12 wt% solution of phosphoric acid for 2 hours at a maximum voltage of 10V so as to form a surface coating of titanium phosphate. Subsequently, the implant was immersed in an aqueous solution of silver nitrate. This results in the formation of some silver phosphate in the titanium phosphate coating.

6. The product recited in independent claim 13 differs from the description of the product of Pickford by reciting the surface layer is an anodized hard layer including pits. The process recited in independent claim 24 differs from the process of Pickford by reciting anodizing at a voltage above 50V. The O'Brien et al patent (hereinafter O'Brien) is directed to the production of medical devices such as stents which may be implanted. The devices have a generally tubular member which includes a porous structure including an oxide of titanium (column 1, lines 50-54). O'Brien also discloses that the invention has utility in other implantable medical devices (column 13, lines 47-49). Titanium is highly desirable because of its high biocompatibility (column 5, lines 33-34). Figures 3A and 3B show the porous morphology that is formed by anodization (column 5, lines 4950). The depth, diameter and spacing of the elements can be controlled by controlling process parameters such as the process time, composition of the chemical bath, circuit voltage, and process temperature (column 6, lines 5-10). Higher temperatures, higher acid concentrations and longer anodization time periods can produce more

porous and, in some cases, softer coatings (column 6, lines 14-16). O'Brien teaches higher voltages yield larger openings. The voltage is typically in the range of about 5 to about 100V (column 6, lines 20-24). The chemical bath can be an acid solution such as a 20 vol % phosphoric solution (column 6, lines 27-32). In the Examples at columns 11 and 12, O'Brien used a 20% phosphoric acid solution and applied voltages ranging from 5 to 100 volts. The pores produced in the anodizing step may be filled with a therapeutic agent. For example a device with larger pores can contain one type of therapeutic agent, while another device with smaller pores can contain a different type of therapeutic agent. The two different therapeutic agents can be delivered into the body at different rates (column 13, lines 55-63).

7. The prior art of record is indicative of the level of skill of one of ordinary skill in the art. It would have been obvious at the time the invention was made to have utilized a voltage of greater than 50V to anodize a titanium implant in a process such as that of Pickford because O'Brien teaches that voltages ranging from lower than that used by Pickford to greater than 50V may be successfully used in forming a porous oxide layer on a titanium implant which may be filled with a bioactive material. As shown by O'Brien, process parameters such as voltage may be varied to obtain an oxide layer with the desired characteristics. Based on the teaching of O'Brien, choice of a higher voltage within the disclosed range would have produced larger openings allowing the incorporation of a greater amount of material into the openings. Choice of a value from within the voltage range disclosed by O'Brien would have been obvious. See MPEP 2144.05.

8. As stated by applicant at page 3, lines 10-15 of the specification, anodizing at a voltage about 50V has two effects: it initially generates a dense hard surface layer whose thickness is

primarily determined by the voltage, and it then generated shallow pits in the surface which are filled with a somewhat softer and more porous material. Use of a voltage at the higher end of the range disclosed by O'Brien and used in O'Brien's examples would have been expected to have resulted in the same surface configuration recited by applicant in claim 13, 21, 22, 23, 24, 32 and 33.

9. With respect to claims 14 and 15, O'Brien discloses the use of pure titanium in the examples. Pickford discloses the use of a titanium alloy (page 1, lines 11).

10. With respect to claim 17, Pickford discloses that the biocidal metal ions are absorbed into the oxide or phosphate matrix formed by anodizing (page 3, lines 33-36).

11. With respect to claims 19 and 24, Pickford discloses that silver, gold, platinum, and palladium are suitable biocidal materials (page 2, lines 20-28).

12. With respect to claim 20, anodizing at 100 V as disclosed by O'Brien and utilized in O'Brien's examples would have been expected to produce a thickness of 0.14 micrometers in the same manner as it does in applicant's process. See page 5, lines 15-17 of the specification.

13. With respect to claims 27 and 28, as noted above, both Pickford and O'Brien disclose anodizing in an electrolyte comprising phosphoric acid having a concentration falling within the range recited by applicant.

14. With respect to claim 31, Pickford discloses that other elements including copper, tin antimony, lead, bismuth and zinc may be used as ions combined into the matrix of oxide of phosphate. See page 2, lines 30-33.

15. Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Pickford et al (WO 03/089023) in view of O'Brien et al (US 7,488,343) as applied to claims 13-15, 17, 19-25, 27, 28 and 31-33 above, and further in view of Rosenberg et al (US 5,185,075).

16. Claim 29 recites that the electrolyte comprises chloride ions at a concentration no more than 500 ppm. The Rosenberg et al patent is directed to a process for anodizing titanium and titanium alloy articles. Table 1 shows that a 5-25 vol % solution of phosphoric acid is a useful anodizing electrolyte. Rosenberg recognizes that halides may be harmful to the anodizing process and suggests the addition of silver nitrate to suppress free chloride. When using silver nitrate for this purpose, the appearance of the yellow silver phosphate signals the excess of silver over halide (column 5, lines 58-63). In example 1 an anodizing voltage of 100 V was applied. It would have been obvious to have controlled the amount of chloride to a small value because Rosenberg teaches than an excessive amount may be harmful to the anodizing process.

17. Claims 13-15, 17, 19-25, 27, 28 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al (US 7,488,343) in view of Pickford et al (WO 03/089023).

18. O'Brien and Pickford are interpreted as above. As previously noted, the pores produced in the anodizing step of O'Brien may be filled with a therapeutic agent. Applicant's claims 13 and 24 differ from O'Brien by reciting that the surface layer incorporates a biocidal material. Pickford teaches that there is a risk of introducing infection when implanting metal implants, and that it has been suggested to include a biocidal material such as silver. The silver can control infection without causing toxic effects to the patient. See page 1, lines 14-19. It would have been obvious to have included a biocidal material in the pores of the implant of O'Brien as

taught by Pickford because the risk of infection would have been reduced. Dependent claims are rejected for the reasons given above.

19. Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al (US 7,488,343) in view of Pickford et al (WO 03/089023) as applied to claims 13-15, 17, 19-25, 27, 28 and 31-33 above, and further in view of Rosenberg et al (US 5,185,075).

20. Rosenberg is interpreted and applied as above. It would have been obvious to have controlled the amount of chloride to a small value because Rosenberg teaches than an excessive amount may be harmful to the anodizing process.

Response to Arguments

21. Applicant's arguments filed January 7, 2010, have been fully considered but they are not persuasive. At page 6 of the Remarks, applicant argues that claim 13 recites "said implant comprising as said surface layer an anodized hard layer including pits in said hard layer, said pits including a softer and more porous material than the hard layer" and points out that claim 24 includes a similar limitation. Applicant argues that nothing in Pickford teaches these recitations such as a dense hard surface layer and also shallow pits in the surface layer, and that nothing in O'Brien and Rosenberg provide the missing recitations. This argument is not convincing. Based on applicant's disclosure, the characteristics recited by applicant result from anodizing a titanium implant in a phosphoric acid solution at a voltage above 50 volts. These are the same conditions disclosed by O'Brien in the examples at column 12, lines 24-35. They are also the same conditions disclosed by Rosenberg. Applicant has offered no cogent explanation as to why the

implant of O'Brien would have different characteristics when the starting material is the same and the process conditions are the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM T. LEADER whose telephone number is (571) 272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Ryan can be reached on 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Leader/
April 24, 2010
/PATRICK RYAN/
Supervisory Patent Examiner, Art Unit 1795